

### **REMARKS/ARGUMENTS**

Applicant has amended Claims 149 and 185. Applicant has cancelled Claims 45, 60, and 157-184, and thus, the objections to and the rejections of Claims 45, 60, and 157-184 are moot. Claims 31-44, 46-59, 131-144, 147-150, 155-156, and 185 are pending. Applicant respectfully requests reconsideration of the pending claims in view of the following remarks.

#### **OBJECTION TO THE SPECIFICATION**

Applicant has amended the title of the invention to "METHODS OF INDIRECTLY STIMULATING THE VAGUS NERVE TO ACHIEVE CONTROLLED ASYSTOLE." Applicant believes this title is clearly indicative of the invention to which the broadest claims are directed, for example, amended independent Claim 185. Applicant respectfully requests withdrawal of the objection to the title.

#### **CLAIM REJECTION – 35 U.S.C. § 112**

Claim 149 stands rejected under 35 U.S.C. § 112, second paragraph, as having insufficient antecedent basis for "into the neck." Applicant has amended Claim 149 to recite "wherein said step of positioning an electrode on the neck of said patient comprises the step of positioning more than one electrode on the neck of said patient." Applicant respectfully requests withdrawal of the rejection of Claim 149.

#### **CLAIM REJECTION – 35 U.S.C. § 102**

##### **Independent Claim 185**

Claim 185 stands rejected under 35 U.S.C. § 102(e) as being anticipated by United States Patent No. 5,913,876 issued to Taylor et al. (hereinafter "Taylor").

Amended Claim 185 specifies "placing an electrode at a suitable location for indirect vagus nerve stimulation."

Taylor discloses the use of minimally-invasive clips that provide precise and efficient electrical contact with the vagus nerve. *Taylor*, col. 5, lines 49-51. The clips of Taylor are considered “minimally invasive” because the clips “bite gently into the nerve to provide positive electrical contact therewith as well as to prevent the clip from falling off the nerve.” *Id.* at col. 7, lines 14-16. Taylor further discloses that “it is important that electrical contact and electrical stimulation be made only with the vagus nerve and not the surrounding vessels, tissues, etc.” *Id.* at col. 7, lines 16-19. As a result, Taylor discloses that the clips must be in direct electrical contact with the vagus nerve.

Accordingly, Taylor does not disclose “placing an electrode at a suitable location for indirect vagus nerve stimulation,” as specified by amended Claim 185. Thus, independent Claim 185 is allowable.

#### CLAIM REJECTIONS – 35 U.S.C. § 103

##### Independent Claim 31

Claim 31 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Taylor in view of United States Patent No. 5,792,187 issued to Adams (hereinafter “Adams”).

Claim 31 specifies “inserting an electrode into the jugular vein of said patient; and actuating said electrode to create an electrical field effective to stimulate said vagus nerve to achieve controlled asystole.”

Taylor teaches the use of minimally-invasive clips that provide precise and efficient electrical contact with the vagus nerve. *Taylor*, col. 5, lines 49-51. The clips of Taylor are considered “minimally invasive” because the clips “bite gently into the nerve to provide positive electrical contact therewith as well as to prevent the clip from falling off the nerve.” *Id.* at col. 7, lines 14-16. Taylor further teaches that “it is important that electrical contact and electrical stimulation be made only with the vagus nerve and not the surrounding vessels, tissues, etc.” *Id.* at col. 7, lines 16-19. As a result, Taylor teaches that the clips must be in direct electrical contact with the vagus nerve. In other words, Taylor specifically teaches away from having an electrode in contact with vessels surrounding the vagus nerve.

Adams teaches a pain control system 10 that provides pain-reducing vagus nerve stimulation before a cardioversion/defibrillation countershock is delivered by an implanted device. *Adams*, Abstract; col. 4, lines 24-26; col. 3, lines 1-3. A catheter 40 bearing an intravascular electrode 36 is threaded to a position within the right internal jugular vein 18 such that the electrode 36 is proximate to the right vagus nerve 16. Similar implantation of a catheter 42, bearing an intravascular electrode 38, brings the electrode 38 within the left internal jugular vein 14 proximate to the left vagus nerve 12. *Id.* at col. 4, line 62 to col. 5, line 5; Figures 1 and 2. Adams also teaches that similar advantages are foreseen using cutaneous or subcutaneously placed patches for long-term prospective pain relief stimulation. *Id.* at col. 5, lines 48-51. More specifically, as shown in Figures 1 and 2, Adams teaches the use of subcutaneous electrodes 37, 39 and external skin electrodes 66, 68. *Id.* at col. 5, lines 9-16 and lines 36-39. Accordingly, Adams only teaches the use of indirect stimulation of the vagus nerve (*i.e.*, through other tissue, veins, and/or the skin) and only for the purpose of pain relief. Adams does not teach or suggest vagus nerve stimulation for the purpose of stopping the beating of the heart, because the only problem Adams was attempting to solve was relieving pain when the heart is already in fibrillation (*i.e.*, the heart needs to be shocked to beat again, not to be stopped from beating).

In light of the above, Taylor and Adams cannot be combined under 35 U.S.C. § 103, because Taylor teaches away from Adams. Adams teaches methods of stimulating the vagus nerve without actually contacting the vagus nerve, while Taylor teaches that electrical stimulation must be made only with the vagus nerve and not the surrounding vessels, tissues, etc. Also, as discussed in the background section of the Taylor reference, Taylor et al. were aware of indirect vagus nerve stimulation being used to alleviate pain, as taught in United States Patent No. 5,458,625 issued to Kendall (hereinafter "Kendall"). *Taylor*, col. 2, line 62 to col. 3, line 3. Kendall teaches the use of transcutaneous electrode pads to indirectly stimulate the vagus nerve in order to alleviate pain. *Kendall*, Abstract. Accordingly, Taylor et al. were already aware of prior art teaching the use of indirect vagus nerve stimulation to alleviate pain (very similar to the Adams reference being cited by the Examiner). However, in the detailed description section of the Taylor reference, Taylor et al. specifically teach that for the purpose of stopping the beating of the heart during surgery, the electrical stimulation must be made directly to the vagus nerve, regardless of how vagus nerve stimulation had been performed in the past to alleviate pain.

In addition, there is no motivation to combine Adams with Taylor. The motivation to combine two references under 35 U.S.C. § 103 must be found in one or both of the references themselves. No such motivation can be found in either the Taylor or Adams references. Adams only teaches the use of a stimulation system for controlling pain during defibrillation. Adams makes no mention of using the stimulation system for stopping beating of the heart or for achieving controlled asystole. Taylor teaches that the indirect simulation methods of Adams, while possibly suitable for pain relief, are not suitable for stopping the beating of the heart. As a result, there is no motivation to combine the references, and one of ordinary skill in the art upon reading these two references would not be motivated to alter the teachings of Taylor with the teachings of Adams.

In light of the arguments set forth above, Applicant respectfully submits that Taylor and Adams cannot be combined under 35 U.S.C. § 103 to teach “inserting an electrode into the jugular vein of said patient; and actuating said electrode to create an electrical field effective to stimulate said vagus nerve to achieve controlled asystole,” as specified by Claim 31. Therefore, independent Claim 31 and dependent Claims 32-44 and 147-148 are allowable.

#### Dependent Claims 32-44 and 147-148

Claims 32-44 and 147-148 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Taylor in view of Adams. Claims 32-44 and 147-148 depend from Claim 31, and are therefore allowable for the reasons set forth above with respect to Claim 31. Claims 32-44 and 147-148 specify additional patentable subject matter not specifically discussed herein.

#### Independent Claim 46

Claim 46 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Taylor in view of Adams.

Claim 46 specifies “positioning an electrode on the neck of said patient; and actuating said electrode to create an electrical field effective to stimulate said vague nerve to achieve controlled asystole.”

Taylor teaches the use of minimally-invasive clips that provide precise and efficient electrical contact with the vagus nerve. *Taylor*, col. 5, lines 49-51. The clips of Taylor are considered “minimally invasive” because the clips “bite gently into the nerve to provide positive electrical contact therewith as well as to prevent the clip from falling off the nerve.” *Id.* at col. 7, lines 14-16. Taylor further teaches that “it is important that electrical contact and electrical stimulation be made only with the vagus nerve and not the surrounding vessels, tissues, etc.” *Id.* at col. 7, lines 16-19. As a result, Taylor teaches that the clips must be in direct electrical contact with the vagus nerve.

Adams teaches a pain control system 10 that provides pain-reducing vagus nerve stimulation before a cardioversion/defibrillation countershock is delivered by an implanted device. *Adams*, Abstract; col. 4, lines 24-26; col. 3, lines 1-3. As shown in Figures 1 and 2, Adams teaches the use of external skin electrodes 66, 68 on the patient’s neck. *Id.* at col. 5, lines 9-16 and lines 36-39. However, Adams only teaches the use of indirect stimulation of the vagus nerve (*i.e.*, through tissue and skin) and only for the purpose of pain relief. Adams does not teach or suggest vagus nerve stimulation for the purpose of stopping beating of the heart, because the only problem Adams was attempting to solve was relieving pain when the heart is already in fibrillation (*i.e.*, the heart needs to be shocked to beat again, not to be stopped from beating).

In light of the above, Taylor and Adams cannot be combined under 35 U.S.C. § 103, because Taylor teaches away from Adams. Adams teaches methods of stimulating the vagus nerve through the skin and tissue of the neck without actually contacting the vagus nerve, while Taylor teaches that electrical stimulation must be made only with the vagus nerve and not the surrounding vessels, tissues, etc. Also, as discussed in the background section of the Taylor reference, Taylor et al. were aware of indirect vagus nerve stimulation being used to alleviate pain, as taught in United States Patent No. 5,458,625 issued to Kendall (hereinafter “Kendall”). *Taylor*, col. 2, line 62 to col. 3, line 3. Kendall teaches the use of transcutaneous electrode pads to indirectly stimulate the vagus nerve in order to alleviate pain. *Kendall*, Abstract. Accordingly, Taylor et al. were already aware of prior art teaching the use of indirect vagus nerve stimulation to alleviate pain (very similar to the Adams reference being cited by the Examiner). However, in the detailed description section of the Taylor reference, Taylor et al.

specifically teach that for the purpose of stopping the beating of the heart during surgery, the electrical stimulation must be made directly to the vagus nerve, regardless of how vagus nerve stimulation had been performed in the past to alleviate pain.

In addition, there is no motivation to combine Adams with Taylor. The motivation to combine two references under 35 U.S.C. § 103 must be found in one or both of the references themselves. No such motivation can be found in either the Taylor or Adams references. Adams only teaches the use of a stimulation system for controlling pain during defibrillation. Adams makes no mention of using the stimulation system for stopping beating of the heart or for achieving controlled asystole. Taylor teaches that the indirect simulation methods of Adams, while possibly suitable for pain relief, are not suitable for stopping the beating of the heart. As a result, there is no motivation to combine the references, and one of ordinary skill in the art upon reading these two references would not be motivated to alter the teachings of Taylor with the teachings of Adams.

In light of the above, Applicant respectfully submits that Taylor and Adams cannot be combined under 35 U.S.C. § 103 to teach “positioning an electrode on the neck of said patient; and actuating said electrode to create an electrical field effective to stimulate said vague nerve to achieve controlled asystole,” as specified by Claim 46. Therefore, independent Claim 46 and dependent Claims 47-59 and 149-150 are allowable.

#### Dependent Claims 47-59 and 149-150

Claims 47-59 and 149-150 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Taylor in view of Adams. Claims 47-59 and 149-150 depend from Claim 46, and are therefore allowable for the reasons set forth above with respect to Claim 46. Claims 47-59 and 149-150 specify additional patentable subject matter not specifically discussed herein.

#### ALLOWABLE SUBJECT MATTER

Applicant appreciates the Examiner’s allowance of Claims 131-144 and 155-184. However, Applicant respectfully traverses the Examiner’s statement on page 7 of the Office Action that “Taylor shows stimulating electrodes on both the neck and in the jugular vein for

stimulating the vagus nerve....” Figure 22 of Taylor only shows stimulating electrodes directly attached to the vagus nerve, not on the neck or in the jugular vein. If the Examiner meant to refer to the teaching of Figure 2 of Adams, Applicant agrees that the jugular vein electrode 38, the subcutaneous electrode 39, and the external skin electrode 68 each correspond to separate embodiments of the Adams invention shown concurrently in Figure 2.

CONCLUSION

In light of the above, Applicant respectfully requests reconsideration and allowance of Claims 31-44, 46-59, 131-144, 147-150, 155-156, and 185.

Respectfully submitted,

A handwritten signature in black ink, reading "Raye L. Daugherty". The signature is fluid and cursive, with the first name "Raye" and last name "Daugherty" clearly legible.

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